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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/058,350 04/10/98 SIMMS

D 0942.3840001

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EXAMINER

OWENS JR, H

ART UNIT

PAPER NUMBER

1623

#12

DATE MAILED:

05/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/058,350

Applicant(s)
Simms

Examiner
Howard Owens

Group Art Unit
1623



☒ Responsive to communication(s) filed on Feb 16, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2-11 and 13-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2-11 and 13-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Arguments

5 The following is in response to the amendment filed 2/16/00:

An action on the merits of claims 2-11 and 13-22 is contained herein below.

10 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15 Claim 12 has been canceled by applicant.

Specification

20 **Trademarks and Their Use**

The use of the trademarks TRITON X-100 and TWEEN 20 have been noted in this application and the amendment filed 2/16/00. These trademarks and others not noted in this action should be capitalized wherever they appear and be accompanied by the generic terminology.

30 **35 U.S.C. 112(2)**

The rejection of claim 12 under 35 U.S.C. 112(2) has been overcome through applicant's amendment.

35 **35 USC § 103**

Claims 2-11 and 13-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Sambrook et al. (Molecular Cloning: A Laboratory Manual, Second Edition; Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 1989) in combination with Chomczynski (5,346,994) and newly cited Perlman, U.S. Patent No. 5,098,603.

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Claims 2 - 11 are directed to an RNA isolation reagent comprising at least one nonionic detergent (0.1 - 1.0%), a chelating agent (20 - 250 mM), a phenol (10%-60%), and a phenol stabilizer (15-55%).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicant acknowledges on page 2, third full paragraph, that Sambrook et al. discloses (sections 7.6-7.9) a method for isolating RNA comprising a non-ionic detergent, phenol, RNase inhibitors, and no chaotropic agent. Sambrook et al. does not teach use of solubilizers nor the use of EDTA to inhibit RNA degradation. However, Chomczynski does teach the use of phenol (30%-50%) with a solubilizer (3% - 15%-) at claim 8. Chomczynski does not teach the use of a phenol stabilizer. However, DeBonville et al. (4,833,239) does teach the use of both a stabilizer (8-hydroxyquinoline) and a solubilizer (isopropanol) at column 4, Example 1.

Neither Chomczynski nor DeBonville teach the use of a chelating agent in extracting nucleic acids, however, Perlman teaches (col. 4, lines 37-51) the use of chelators such as EDTA

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when performing nucleic acid extractions with phenolic solutions to remove traces of divalent metal ions, some of which are known to catalyze the oxidation of phenol; moreover, Perlman further teaches that when even minute traces of metal ions are present, phenol solution is prone to catalytic oxidation, which adequately bridges the nexus between the differences in the prior art and the invention as claimed (and counters applicant's assertion in the instant specification on p. 4, line 26 that the use of chelators to protect nucleic acids is novel).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the selected reagents in kit form to extract RNA.

The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). A person of ordinary skill in the art would have been motivated to combine the teachings of Perlman regarding the inclusion of a chelator with phenolic solutions with the nucleic acid extraction reagents of DeBonville and Chomczynski to prevent the oxidation of phenol by divalent metal ions.

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Any inquiry concerning this communication or earlier
5 communications from the examiner should be directed to Howard Owens
whose telephone number is (703) 306-4538 . The examiner can normally be
reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

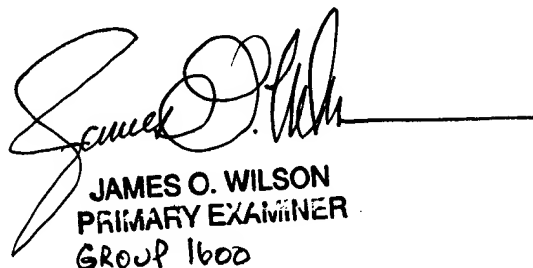
If attempts to reach the examiner by telephone are unsuccessful,
the Primary Examiner signing this action, James O. Wilson can be reached
10 on (703) 308-4624 . The fax phone number for this Group is (703) 308-
4556.

Any inquiry of a general nature or relating to the status of this
application or proceeding should be directed to the Group receptionist
whose telephone number is (703) 308-1235.

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Howard Owens
Group 1623

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JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600